

DEC 1 9 2000

K002927

**SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
POLYPECTOMY SNARES « DISPO'LOOPS »**

Submitted by

ODON LifeTechnology s.a
2 bis, rue du commandant Pilot
92200 NEUILLY SUR SEINE - France
Phone : 00 33 1 47 22 16 30
Facsimile : 00 33 1 47 22 77 19
e-mail : jpd@club-internet.fr

Identification of a Legally Marketed Predicate Device

The ODON LifeTechnology polypectomy snares « Dispo'Loops » are substantially equivalent to the single use polypectomy snares from following US companies, which are legally marketed and distributed pursuant to 510(k) :

INSCOPE, LLC	K992477
MILL ROSE Lab.	K971275
UNITED STATES ENDOSCOPY	K970356
LIGHTHOUSE MEDICAL inc.	K960230
MILL ROSE Lab.	K951600
MEDI GLOBE Corp.	K943935
BOSTON SCIENTIFIC	K950496
BOSTON SCIENTIFIC	K941750
ENDO VATIONS	K942110
INTL, MEDICAL, Inc.	K940335

Device Description

The ODON LifeTechnology polypectomy snares « Dispo'Loops » consist of an actuation handle. The loop is attached to the actuation handle by means of a cable. A monopolar electrical connector is provided on the handle and is electrically connected to the snare loop. A flexible sheath is fixed on the handle and covering the cable assuming junction in between handle and snare loop.

The ODON LifeTechnology polypectomy snares « Dispo'Loops » may be used with most monopolar electrosurgical generators. The polypectomy snares have a universal connector which is compatible with main active cord connectors such as Boston Scientific, Olympus, Wilson Cook

J. Duval

2 bis rue du commandant Pilot - 92200 NEUILLY SUR SEINE France
Téléphone : (33) 1.47.22.16.30 Fax : (33) 1.47.22.77.19 E-Mail : jpd@club-internet.fr



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 19 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. J. M. Durand
President
Odon Life Technology
30, Avenue de l'amiral Lemonnier
78160 MARLY LE ROI
FRANCE

Re: K002927
Dispo'Loop Polypectomy Snares
Dated: September 07, 2000
Received: September 20, 2000
Regulatory Class: II
21 CFR §876.4300/Procode: 78 FDI

Dear Mr. Durand:

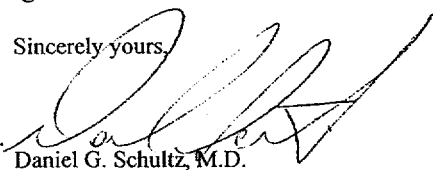
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002927

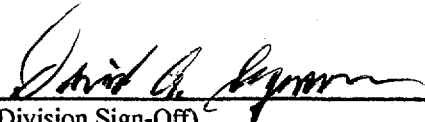
Device Name: Dispo'Loop Polypectomy Snares

Indications For Use: Dispo'Loop monopolar polypectomy snares are intended to electrosurgically remove polyps from the colon in conjunction with an electrosurgical generator via a flexible endoscope.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002927

Prescription Use
(Per 21 CFR 801.109)